

REMARKS

Claims 1, 3 and 7-17 are currently pending in the subject application and have been examined on the merits. Claims 1, 3 and 7-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stovall (WO 99/04720, hereinafter “Stovall”) in view of Murphy (WO 00/29553, hereinafter “Murphy”).

Applicants respectfully traverse this rejection. For reasons set forth in Applicants’ responses filed on January 17, 2006 and on June 29, 2006, Applicants respectfully submit that the claims are patentable over Stovall and Murphy.

In any event, Applicants respectfully submit that the Office Action misconstrues the presently pending claim limitations and misapplies the teachings of Stovall/Murphy. Applicants’ claim 1 reads:

1. A method for repairing an intervertebral disc of a patient using a cultured connective tissue construct, comprising:
 - (a) forming at least one opening in the annulus fibrosis of the intervertebral disc;
 - (b) removing at least a portion of the nucleus pulposus through the opening in the annulus fibrosis; and
 - (c) grafting a bioremodelable cultured connective tissue construct to close the opening in the annulus fibrosis in the absence of exogenous matrix components or synthetic members,
*said tissue construct comprising
an extracellular matrix layer and
cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members.*

Thus, the underlined limitation, which was added in Applicants’ most recent June 29, 2006 Amendment, recites that the opening in the annulus fibrosis is closed in the absence of

exogenous matrix components or synthetic members. Similar grafting/closing limitations were also added to Applicants' independent claims 10 and 13. This underlined grafting/closing limitation has nothing to do with tissue construct, the limitation of which is recited in *italics*. And it is this specific underlined grafting/closing limitation that is absent in the improper combination of Stovall and Murphy.

That is, Stovall teaches and suggests a method for treating a ruptured intervertebral disc which comprises (1) aspirating all or part of a cell-containing gel from the disc, (2) excising the damaged tissue from the annulus fibrosis of the ruptured disc leaving a hole, (3) covering the hole with a layer containing cells attached to a porous matrix comprising a crosslinked biocompatible polymer and (4) injecting a cell-containing suspension into the disc. In other words, Stovall requires the use of a biocompatible polymer (*i.e.*, a synthetic member) to cover the opening or hole. (*e.g.*, p. 2, lines 10-18; p. 6, line 11 – p. 8, line 3; p. 10, line 16-p. 11, line 4). Thus, Stovall does not teach or suggest Applicants' underlined limitation of closing the opening in the ruptured disc in the absence of exogenous matrix components or synthetic members.

And even if Murphy teaches a method for producing the specific *tissue constructs* without exogenous matrix components or synthetic members as recited in Applicants' claims (*i.e.*, the *italicized* limitation), it fails to make up for this underlined grafting/closing limitation deficiency. That is, Murphy has nothing to do with Applicants' aforementioned underlined grafting/closing claim limitation. Rather, Murphy is only relevant to the following *italicized* limitation of Applicant's claims: "*said tissue construct comprising an extracellular matrix layer and cultured fibroblast cells that synthesize and assemble the layer of extracellular matrix in the absence of exogenous matrix components or synthetic members.*"

In summary, the grafting/closing step and the *tissue construct* are two separate limitations in Applicant's claims, and both elements must be free of exogenous matrix components or synthetic members. Stovall requires the use of a synthetic member in its grafting/closing step and Murphy is only relevant to the *tissue construct*. Thus, the asserted Stovall/Murphy combination still fails to teach Applicant's underlined grafting/closing step in the absence of exogenous matrix components or synthetic members.

In light of the foregoing, the application is now believed to be in proper condition for allowance and a Notice to that effect is respectfully requested. If this *Response To Office Action* does not otherwise result in the issue of such Notice, the Examiner is respectfully invited to contact the Applicants' undersigned counsel for an interview.

No extra fee is believed due. However, if any additional fees are necessary, the Director is hereby authorized to charge such fees or credit any overpayment to Deposit Account No. 50-0540.

Respectfully submitted,

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